No. 2008-1511, -1512, -1513, -1514, -1595

In the

United States Court Of Appeals

For The Federal Circuit

THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.) and ABBOTT LABORATORIES,

Plaintiffs-Appellants,

v.

BECTON, DICKINSON AND COMPANY, and NOVA BIOMEDICAL CORPORATION,

Defendants-Appellees,

and

BAYER HEALTHCARE LLC,

Defendant-Appellee.

Appeal from the United States District Court for the Northern District of California in consolidated case nos. 04-CV-2123, 04-CV-3327, 04-CV-3732, and 05-CV-3117, Judge William H. Alsup.

BRIEF OF PLAINTIFF-APPELLANTS ABBOTT LABORATORIES AND ABBOTT DIABETES CARE, INC.

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UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Therasense v. Becton

No. 2008-1511, -1512, -1513, -1514, -1595

CERTIFICATE OF INTEREST

Counsel for the (petitioner) (appellant) (respondent) (appellee) (amicus) (name of party) Abbott Diabetes Care Inc. and Abbott Laboratories certifies the following (use "None" if applicable; use extra sheets if necessary):

1. The full name of every party or amicus represented by me is:

Therasense, Inc. (now known as Abbott Diabetes Care, Inc.) and Abbott Laboratories

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

See attachment

9/29/08
Date

Signature of counsel

Rohit Singla
Printed name of counsel

Please Note: All questions must be answered

cc: Bradford Badke, Esq., Morton Amster, Esq. and Rachel Krevans, Esq.

CERTIFICATE OF INTEREST ATTACHMENT

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

MUNGER, TOLLES & OLSON LLP	Jason Rantanen Jeffrey I. Weinberger Rohit K. Singla John Peck (no longer at MTO) Ted G. Dane Bill Ward
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Statement of Related Cases

1. There have been no prior appeals from the district court proceedings.

2. Abbott has also appealed the district court's September 10, 2008 judgment n favor of BD/Nova regarding Patent Nos. 6,592,745 and 6,143,164, respectively. Pursuant to this Court's September 23, 2008 Order, Abbott has addressed the issues relating to the '745 (and '164) patents in this brief, and will shortly be moving to consolidate the appeal of that Judgment with the instant appeal.

Abbott has also appealed the district court's August 8, 2008 judgment in favor of BD/Nova regarding Patent No. 5,628,890.

3. On August 21, 2008 the district court declared this an exceptional case based on its inequitable conduct finding. That determination has not yet been appealed but any appeal would be related to the instant appeal.

I. INTRODUCTION

This appeal concerns three patents claiming critical technology in the field of diabetes blood glucose test strips: Patent Nos. 5,820,551 ("the '551 patent"), 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent"). With respect to each patent, the district court made the same kind of fundamental error: reading isolated statements out of context and in the abstract without reference to the patent as a whole. The district court often acted as its own expert and disregarded the actual *technical teachings* of the prior art and the testimony of experts, inventors, and other scientific witnesses.

The '551 patent claims disposable strips for testing glucose levels in ***whole blood*** that use biosensors without a membrane. The district court held the patent obvious based on one sentence in a prior art patent, No. 4,545,382 ("the '382 patent"), that describes a membrane as "optional" or "preferred." From this alone, the district court concluded the '382 rendered obvious a membraneless sensor for blood — even though (1) every technical teaching in the '382 patent suggests otherwise, (2) the '382 inventors testified they had not known how to build such a sensor, and (3) nothing in the '382 patent would have enabled anyone to practice the '551 invention. The district court then combined that membraneless sensor with other prior art references to arrive at the '551 invention: an elongated

disposable blood-glucose strip designed for releasable attachment to a meter with a two-electrode electrochemical sensor that is covered by a single drop of blood.

The district court also held the '551 patent unenforceable — based on the failure to disclose not prior art, technical data, or test results, but *legal briefs* submitted by German patent counsel regarding the European counterpart of the '382 patent. The court read two passages in these European briefs as inconsistent with statements made to the PTO in the '551 prosecution. The district court's interpretation of the legal briefs was not only incorrect – it was irrelevant to the issue of inequitable conduct, which involves whether Abbott's patent counsel and scientist had at least a reasonable interpretation of those documents. They did. Inequitable conduct cannot be premised on a close reading of at best ambiguous legal briefs.

The '164 and '745 patents claim advanced electrochemical biosensors for analyte measurement in very small blood samples, less than 1μL. The district court construed a shared claim limitation — a sample held in a "*non-flowing* manner" — so as to exclude any movement, even the convective motion present in all liquids. Needless to say, this unduly restrictive interpretation of the claims finds no support in the specifications, prosecution history, or common sense.

Finally, the district court held the '745 anticipated on summary judgment, based (again) on one sentence in the prior art '225 reference, which states that *non-*

leachable chemical mediators are "preferred." From this alone, the district court concluded the '225 reference taught the use of *leachable* mediators — even though *Defendants' expert* opined to the contrary.

II. JURISDICTIONAL STATEMENT

The district court had subject-matter jurisdiction under 28 U.S.C. § 1338(a). This Court has jurisdiction under 28 U.S.C. §§ 1291 and 1295.

The district court entered judgment under Rule 54(b) as to the '551 with respect to Bayer and BD/Nova on July 2, 2008, as to the '551 and '745 with respect to Bayer on August 18, 2008, and as to the '745 and '164 with respect to BD/Nova on September 10, 2008. (JA1-2.3.) Abbott timely filed notices of appeal on July 21, July 31, September 12, and October 8, 2008. (JA7655-JA7664; JA13835-36.)

III. STATEMENT OF THE ISSUES

1. Whether the '551 invention was obvious based on a single sentence in a prior patent, unsupported by specific teachings and absent clear and convincing evidence that the prior patent enabled the '551 invention.

2. Whether the '551 patent was unenforceable based on the failure to disclose attorney arguments made to the European Patent Office in connection with a prior art patent, where the lawyer and scientist believed the briefs were not inconsistent with the positions taken before the PTO.

3. Whether the "non-flowing manner" limitation in the '745 and '164 patents should be construed to render the claims inoperative.

4. Whether the '745 patent could be held anticipated on summary judgment based on prior art that Defendants' own expert testified did not disclose the '745 invention.

IV. STATEMENT OF THE CASE

In March 2004, Becton Dickinson and Company ("BD") sued TheraSense, now a subsidiary of Abbott Laboratories ("Abbott"), seeking a declaratory judgment of non-infringement of the '745 and '164 patents. (JA11455.) TheraSense and Abbott subsequently counter-sued BD and its supplier, Nova Biomedical, on those patents, as well as the '551 patent and Patent No. 5,628,890 ("the '890 patent"). (Trial Order 1.)[1] In August 2005, Abbott sued Bayer Healthcare for infringement of the '551 and '745 patents. (JA420.) The Bayer and BD/Nova cases were subsequently coordinated. (Trial Order 2.)

The district court issued two claim construction orders, one involving the '164 and '890 patents, and one involving the '551 and '745 patents. On April 3, 2008, the district court held numerous claims of the '745 patent to be anticipated on summary judgment. (SJ Order 47-49.) The district court also granted BD/Nova

[1] The Summary Judgment and Trial Orders are attached as Addendums 4-5.

summary judgment of non-infringement of the '745 and '164 patents based on the "non-flowing manner" limitation. (*Id.* 21-24.)

From May 27 to June 3, 2008, a bench trial was held on Defendants' defenses with respect to the '551 patent. (Trial Order 2-3.) On June 24, the court held claims 1-4 of the '551 patent to be obvious. (Trial Order 54.) The district court also held the '551 patent unenforceable due to inequitable conduct. (*Id.*)

After this appeal was taken, the district court held the '551 litigation was an exceptional case and authorized attorneys' fees to Defendants based on the inequitable conduct determination. Defendants' fee claims for approximately $20 million are currently pending before the district court.

V. STATEMENT OF FACTS

A. Background of the Technology

1. MediSense

Diabetics today rely on cheap and accurate home glucose sensors to manage their disease. Those sensors are the result of pioneering work done at MediSense, formerly known as Genetics International and now part of Abbott. (Trial Order 3-5.) At the time of the events at issue, the early 1980s, MediSense was a start-up in Oxford, England with one of the leading research groups in this field in the world. (Trial Order 3-4; JA2610 at 300; JA3726.) Prior to the ground-breaking work at

MediSense, diabetic patients relied on "colorimetric" optical systems in which patients estimated blood glucose levels by evaluating the color produced by a chemical reaction. (JA3715-16, 3718; JA2615 at 320.) Such systems were unreliable and inconvenient. (*Id.*)

MediSense made several inventions — including those claimed in the '382 and '551 patents — that resulted in blood glucose test strips using electrochemical biosensors. (Trial Order 4-5.) MediSense's first commercial product was the Exactech in 1987. (*Id.* 50.) Exactech was the first disposable electrochemical test strip on the market, and MediSense sold over one billion Exactech strips. (JA2640 at 422:21-423:13; JA3725.) It was a revolutionary product, transforming diabetes management and creating a $3-4 billion industry in the U.S. alone. (JA2614 at 316:19-25.)

2. TheraSense

TheraSense was another ground-breaking start-up that invented in the late 1990's electrochemical biosensors that required less than 1μL of blood. Such a small sample size permits more frequent testing and less painful blood draws from less sensitive areas of the body. (JA13596-98.) These advances have been especially beneficial to diabetic children who must test their glucose levels repeatedly everyday. (*Id.*) TheraSense's founder Adam Heller received the

National Medal of Technology and Innovation for his work on TheraSense sensors.[2] Abbott acquired TheraSense in 2004 for $1.12 billion.

3. Electrochemical sensors

In the electrochemical biosensors of the inventions in suit, glucose in blood reacts with, and transfers electrons to, an enzyme. (Trial Order 8.) A mediator transfers the electrons from the enzyme to a sensor's "active electrode." (*Id.*) The electrons flow through a meter attached to the sensor, which calculates the glucose concentration based on the current flow. (*Id.*) The mediator and enzyme are generally coated on the active electrode itself. (*Id.*)

Electrochemical glucose sensors are not limited to testing blood. They can measure glucose levels in a variety of liquids, including (a) whole blood (or simply "blood"); (b) blood plasma (the liquid component of blood without red blood cells); (c) interstitial fluid (the liquid between cells in the skin or other organs); and (d) buffer solution. (*See, e.g.,* JA2619 at 337:22-338:3 (blood plasma); JA122 2:40-45 (blood); JA6508 at 3:57-4:2 (interstitial fluid); JA6510-11, Example 8 (buffer).)

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[2] Press Release, (Aug. 25, 2008), at www.uspto.gov/web/offices/com/speeches/08-19-2008ir.htm.

B. The MediSense Patents

1. The '382 patent: A faster mediator

The first advance by MediSense's scientists is described in the '382 patent, which issued in October 1985, but claims priority to an October 23, 1981 United Kingdom application. (Trial Order 4.) It claims electrochemical biosensors using faster ferrocene-based mediators. (Trial Order 9-10.) The '382 invention itself was a tabletop device using three electrodes in glass test tubes rather than consumer-ready sensors. (JA2997-98 at 701:8-705:25; JA6510 7:4-12; JA6505 Fig. 1; JA6509 5:54-56.) The goal of the '382 patent was to develop "an implantable glucose sensor," not a disposable test strip. (JA6507 at 1:15-25.)

2. The continuing need for a membrane

Before the faster mediators of the '382 patent, electrochemical sensors used *diffusion-limiting* membranes. (Trial Order 14.) These membranes, also described as "glucose controlling" or "semipermeable," reduced the rate at which glucose contacted the sensor chemistry and electrodes because the older mediators could not cope with a rapid influx of glucose. (JA2742 at 509:23-510:25; JA3002 at 721:14-24; JA6511.) Diffusion-limiting membranes were difficult to manufacture and greatly increased the time for measurement. (*Id.*) The faster mediators of the '382 patent eliminated the need for diffusion-limiting membranes. (JA3002-3 at 721:11-725:2.)

The '382 technology did require a different kind of membrane — a "protective" or "permeable" membrane — at least in certain circumstances. First, measurements *in whole blood* (as opposed to blood plasma, interstitial fluid, or buffer) required protective membranes to prevent "fouling," *i.e.*, red blood cells from sticking to the electrodes and interfering with the electron transfer from the mediator to the active electrode. (Trial Order 16-17; JA2733 at 473:3-474:12; JA2740 at 499:18-23.) Second, sensors injected into the human body (*in vivo*) used protective membranes to prevent the chemistry from dissolving into the body. (Trial Order 16-17.) Importantly, protective membranes do not interfere with the flow of, and are *fully permeable* to, glucose molecules, which are much smaller than red blood cells. (JA2733 at 473:3-474:6; JA2738 at 493:8-494:8.)

The '382 sensors did not, however, require a membrane for interstitial fluid or buffer, and the '382 patent describes membraneless sensors for such applications. (JA6508 3:57-4:2; JA6510-11, Example 8.)

3. The '551 patent: Disposable test strips for *whole blood* using sensors *without a membrane*

The original application leading to the '551 patent was filed in May 1983 in the United Kingdom. (JA114.) In the year and a half between the '382 and the '551 applications, MediSense's scientists made significant advances. The '551 patent describes a disposable electrochemical test strip, designed for releasable

attachment to readout circuitry, for testing glucose in whole blood using just two electrodes (the '382 used a three-electrode system). (JA122.)

The '551 invention was intended for whole blood: the claims specifically involve whole blood samples and require the electrodes to be "covered by a single drop of whole blood." (JA128 at 13:29-14:47.) Although it is intended for use with whole blood, the detailed instructions for the preferred '551 embodiment (Figures 1-7) do not include a membrane. (JA125 8:35-51.) The PTO ultimately found the '551 patent patentably distinguishable from the '382 patent because, unlike the '382 patent, it taught a sensor for whole blood without a membrane. (Trial Order 7.)

C. There Is No Evidence That the '382 Patent Taught a Sensor for Whole Blood Without a Membrane.

The court's '551 obviousness ruling relied on its theory that the '382 patent taught PHOSITAs (persons having ordinary skill in the art) to make and use membraneless sensors for whole blood. (Trial Order 20.) It then combined that membraneless sensor with other prior art references to arrive at the '551 patent. The district court accepted that prior to the '382 patent, PHOSITAs would have used a membrane for blood. (*Id.* 14.) Thus, the critical issue is whether the '382 taught contrary to that conventional wisdom.

1. The '382 embodiments all use a membrane for whole blood.

The 13 Examples. The district court conceded that although the '382 patent "contained *thirteen* working examples of preferred embodiments of the invention," each "example[] involving blood employed a membrane." (Trial Order 10-12 (emphasis added).) This fact bears repeating: in **13** working examples, there are none without a membrane for blood. The district court dismissed this as "happenstance." (*Id.* 16.) Here, the district court began its habit of acting as its own expert: No one at trial testified this was happenstance. Nor did the district court or any defense expert explain why, if the inventors intended such a device to be part of their invention, a membraneless sensor for whole blood was not expressly described,.

Example 8. The '382 specification actually teaches away from membraneless sensors for whole blood. In Example 8, a sensor is constructed without a membrane and tested in buffer solution, *i.e.*, in the absence of red blood cells. (JA6510-11.) That sensor was then "modified" by adding "a cellulose acetate membrane" before testing in buffer and ***blood.*** (Trial Order 12; JA6511 9:25-33.) Even though Defendants' expert claimed that testing in blood was "what the whole example is about," ***the version of the sensor without the membrane was conspicuously never tested in blood.*** (JA2534 at 250:19-20.)

The district court got around Example 8 by effectively acting as its own expert and claiming that "a membrane was added . . . little more than [as] a way to investigate the time effect of adding a membrane." (Trial Order 16.) This interpretation of Example 8 was not supported by the testimony of any witness or any other evidence. To the contrary: the goal of the Example was testing in blood, the specific omission of a test of the membraneless sensor in blood would have been important to PHOSITAs. (JA2739 at 497:4-498:21.)

Membraneless Embodiment for Non-Blood. The district court cited a passage in which a "different form of the invention" is described without a membrane. (Trial Order 9-10.) But tellingly, this membraneless sensor was "envisaged" for "projecting only into the dermis" — *i.e.*, for interstitial fluid, ***not blood***. (*Id.* 10; JA2740 at 502:13-18; JA2994-95 at 691:20-692:2.)

2. The '382 inventors did not themselves know how to test in whole blood without a membrane.

The district court ignored the uniform testimony from the inventors — even an inventor paid by Defendants — that they themselves did not know how to make a membraneless whole blood sensor at the time of the '382 application, and only figured that out during the research for the '551 invention. Neither the district court nor Defendants explained how the '382 patent could disclose something to a

PHOSITA that the inventors themselves did not understand, particularly given that the MediSense inventors were worldwide leaders in this field.

Professor Hill, an inventor on both patents, testified the inventors did not know whether a membraneless sensor for whole blood was possible in 1981, much less how to build such a sensor. (JA3215-17.) As far as he knew, even after the '382 application "there were no electrodes that could be introduced into blood without a membrane." (JA3209.) Even a year later, the inventors merely thought such a sensor theoretically *possible*: they "had some experiments that suggested that it was possible." (JA3217.) The testimony of Graham Davis, an inventor on the '551 patent, was to the same effect. (JA3085-87.)

Professor Higgins, an inventor and *paid witness for Defendants*, testified that the experiments by the research team in February 1983 were still using a membrane for blood. (JA3721; JA3724; JA3729-31.) He did not recall that the inventors knew how to build a membraneless sensor for whole blood at the time of the '382 application. They simply thought it "quite *conceivable* that it would be *possible*." (JA3746 at 119:17-23 (emphasis added).)

The inventor testimony is supported by the June 1986 application for Patent No. 4,897,173, by Shiro Nankai, another "leader in the field of electrochemical sensors in the early 1980s." (JA3000 at 712:7-9.) In the '173 specification — submitted nine months after the issuance of the '382 patent — a protective

membrane is omitted when testing in blood plasma but *a membrane is added when testing in whole blood.* (JA3000 at 712:17-24; JA6362-63, Examples 3-4.) The district court agreed the Nankai patent "did tend to support the 'conventional wisdom' argument advanced by Abbott," but nonetheless disregarded the Nankai reference on unsupported speculation that Nankai might not have known about the '382 patent. (Trial Order 19.)

3. There is no evidence the '382 embodiment would work in blood without a membrane.

The district court based its conclusion that the '382 sensors would have worked in blood without a membrane because "the chemistry was fast enough (at least by the time of the '382 prior-art disclosure) to obtain acceptable results without a membrane." (Trial Order 20-21.) Once again, no evidence supports the court's conclusion. Neither the inventors, the expert witnesses, nor any other witness so testified.

There is no evidence that the membraneless sensor of Example 8, for example, would have worked if a PHOSITA had even thought to have tried it in whole blood. Defendants' expert, Dr. Turner, who was part of the MediSense research team, did not opine that any membraneless sensor from the '382 patent worked in whole blood without a membrane. All he could say was that the '382 does not expressly state that the membraneless sensor would *not* work in whole

blood, but even that ignores Example 8. (JA2533 at 248:25-249:2.) Such an opinion certainly does not constitute evidence that the '382 taught membraneless sensors for whole blood, let alone clear and convincing evidence. Moreover, Dr. Turner performed no tests to determine whether the membraneless sensor of Example 8 would work in whole blood.

The district court ignored the uncontroverted evidence on this point from Dr. Sanghera, another MediSense scientist, who had done "experiments that replicated what was in the '382 patent" at Medisense. (JA3007 at 741:9-11.) Dr. Sanghera pointed out that Example 8 reports that the membraneless sensor had a 5% oxygen sensitivity when tested in an air-saturated buffer solution as compared to one without oxygen. (JA3001 at 716:12-717:23; JA6511 at 9:19-21.) Because the oxygen level of whole blood is an "order of magnitude higher" than the buffer, this 5% discrepancy indicated that the membraneless sensor *would not work* in oxygen-rich blood. (JA3001 at 717:6-23.) Again, this evidence of lack of enablement was ignored by the district court.

4. There are many differences between the '382 sensors and the sensors used in the '551 test strips.

Acting as its own expert, the district court concluded that the only difference between the '551 and '382 sensors was the absence of a membrane. But that is not correct and no witness so testified. Although it is not clear precisely why the '551

membraneless sensor works in blood, it is undisputed that the exact electrode configuration, the materials used, and how the electrodes are prepared can all be critical. (JA2755-56 at 562-63.) Professor Hill explained that as it "turned out," the inventors ultimately learned that "adsorption," *i.e.,* fouling, "depended very much on the structure of the electrode. If an electrode was very well prepared, then there was relatively little" fouling. (JA3212-14.)

There are many differences in the preparation of the '551 and '382 electrodes, and the district court could not simply presume that the '382 membraneless sensors would have worked in blood like the '551 sensors. First, the '382 patent teaches repeatedly to ***oxidize the electrode***, *e.g.*, "heat[] in an oven for 40 h at 200° C. to give[] a[n] oxidised surface." (JA6511 9:1-3; JA6508 3:22-27; JA6510 8:16.) But the inventors later learned that oxidized electrodes exhibit greater fouling: "If [the electrode] was left in the air for a long time to oxidize, then there was much more" fouling. (JA3212-14.) The '551 patent pointedly does not oxidize the electrodes. (JA125 8:22-51; JA127 12:31-38.) The district court ignored this distinction.

Second, the electrode of Example 8 is an ultracarbon rod, which showed a 5% oxygen sensitivity when tested even in a buffer solution with limited oxygen. *Supra* 15. The '551 patent, by contrast, teaches that electrodes should be constructed from grafoil or screen printing of colloidal carbon, *i.e.*, a carbon

suspension or paste. (JA125 7:15-18; JA127 12:17-40.) When defense expert Dr. Turner worked for MediSense, he reported on their discovery that grafoil showed much less oxygen sensitivity than the ultracarbon rod. (JA6367.) Not coincidentally, grafoil was the electrode material used when inventor Davis exclaimed in his 1983 lab notebook — *after* the application for the '382 was filed — that "We can now test [in] whole blood." (JA6437.)

Continuing to act as its own expert on electrochemistry, the district court dismissed this difference because the '382 patent says its electrodes have "low oxygen sensitivity." (Trial Order 21.) That statement must be read in the context of the invention, which discloses a sensor *with a membrane* for blood. There is no evidence the '382 sensors' "low oxygen sensitivity" was so low that the membrane could be removed in whole blood. The evidence is to the contrary: the membraneless electrode in Example 8 was specifically *not* tested in whole blood and showed a significant oxygen effect.

The district court relied also on testimony that the Exactech used carbon paste, "the same material disclosed in the '382 patent." (Trial Order 22 n.10.) But the Exactech was made using the ***screen printing*** of colloidal carbon taught by the '551. (JA3019 at 788:19-25.) Indeed, the title of the '551 patent is "Strip Electrode with Screen Printing." (JA114.) The '382 does not teach screen printing. The district court ignored this distinction because ***Abbott*** had not proven

that it would affect sensor performance. (Trial Order 22 n.11.) In so doing, the court lost sight of the fact that Defendants bore the burden of proving by clear and convincing evidence that the '382 sensors enabled one to make membraneless sensors for use in blood.

D. The District Court Relied Only on the "Optionally, but Preferably" Language.

Disregarding all of this evidence, the district court held that the '382 patent taught membraneless sensors for blood based solely on one sentence in the specification:

> Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and mediator layers, permeable to water and glucose molecules.

(JA6508 4:63-66.) According to the district court, that sentence by itself taught membraneless sensors *for blood* because it says that the membrane is just "preferred" or "optional." (Trial Order 15.) ***The negative implication from the words "optional" and "preferred" is the entire basis of the district court's obviousness ruling.***

The district court, like Defendants' expert, relied on the supposed "plain language" of that sentence. (JA2531 at 239:20-22.) In doing so, it improperly focused on a single word to the exclusion of the rest of the patent disclosure, which provides the necessary context for this statement.

First, the sentence provides the key disclosure that the membrane used in the '382 sensors is "permeable to water and glucose," *i.e.*, that it is not the diffusion-limiting membrane previously used. This was the focus of the EPO proceedings discussed below. *Infra* 23-24.

Second, it is undisputed that the protective membrane was optional where there are no red blood cells, such as interstitial fluid, blood plasma, and buffer. Not coincidentally, the '382 patent has examples of membraneless sensors but only for use in such fluids. (JA6508 3:57-4:2; JA6510-11, Example 8.) This resulted from the '382's faster chemistry; glucose-limiting membranes otherwise would have been required in all applications. In the context of the entire specification and prior art, the sentence does not mean a membrane is always optional, but rather that a membrane is not necessary in all applications.

Third, by referring to the use of a membrane in whole blood as "preferable," rather than "necessary," the inventors considered themselves to have invented a membraneless sensor in whole blood. This conclusion was ill-founded. Witnesses *on both sides* agreed that terms like "optionally" and "preferably" are not always read literally in patent specifications. Abbott's patent prosecutor, Lawrence Pope, explained that he understood the "optionally, but preferably" phrase, at least as applied to whole blood, to be terms of art, or "patentese." (JA2978-79 at 627:22-628:20.) Any other interpretation would be inconsistent with the uniform technical

teachings throughout the '382 patent that use membranes for whole blood. Pope, a patent prosecutor with over 35 years of experience, explained that patent prosecutors often use such words instead of terms like "required" or "needed" to avoid limitations in the specification from being improperly read from the specification into the claims: "one, in drafting a patent application, wants to be careful not to be unduly restrictive. And so one uses permissive words like 'preferable' and 'may' to avoid being unduly restrictive." (JA2978-80 at 627:25, 632:7-11.)

Defendants' own expert, Dr. Turner, acknowledged the role of patentese.[3] He agreed, for example, that a PHOSITA would understand the sentence, "'[p]referably, the sensor has at least one electrode besides the active electrode,'" to mean a second electrode was ***required***, not merely preferred. (JA2623 at 353:7-17.) PHOSITAs read such language in the context of the whole patent and conventional wisdom. Indeed, as discussed *infra* 60-62, in challenging the validity of the '164 patent, Turner himself opined that the sentence "preferably, the redox mediators of the present invention are bound or otherwise immobilized" did ***not*** contemplate the use of nonimmobilized, leachable mediators. Rather he said the phrase was

[3] Defendants' patent law expert, Thomas Smegal, pointedly did not dispute that "optional" and "preferred" can be terms of art.

> patent language, or patent tease [sic], . . . I've read a lot of patents over the years that sort of used this sort of language. And what it's trying to tell you is don't use a leachable mediator.

(JA1571 at 139:15-140:1; JA9738:11-14.)

E. The District Court Found Inequitable Conduct Based on a Purported Inconsistency Between Legal Briefs Submitted to the PTO and EPO.

The district court's inequitable conduct ruling is unprecedented. It is based not on withholding of prior art or technical or scientific data relevant to patentability. Instead, the '551 patent was held unenforceable — and a patent lawyer's unblemished career was tarnished — because the district court interpreted arguments made by MediSense's German counsel to the European Patent Office (EPO) regarding the European counterpart of the '382 patent as inconsistent with statements made to the PTO in the '551 prosecution.

1. The statements to the PTO

In the fall of 1997, after Abbott acquired MediSense, Abbott's patent prosecutor Lawrence Pope assumed responsibility for the file that resulted in the '551 patent. He sought new claims for a disposable test strip for measurement in a drop of ***whole blood*** without a membrane. (JA2976 at 618:1-4.) Pope had prosecuted hundreds of patents, both in private practice with highly respected law firms as well as in-house for companies such as appellee Bayer and appellant Abbott. (JA2975-76 at 613:10-616:12) In his 35 years of practice, Pope had never

been even *accused* of inequitable conduct on any of the hundreds of other patents he has prosecuted. (JA2976 at 616:17-20.)

In November 1997, Pope and Examiner Shay met to discuss the "optionally, but preferably" language of the '382 patent. (*Id.* at 619:7-25.) They agreed the '382 patent taught that a protective *permeable* membrane was required for blood, *i.e.*, that the "the overall teaching of this document, including this language," was that the '382 sensor needed "a protective membrane which protected the sensor from some of the components of human blood, like erythrocytes, but which allowed free access of glucose and water across the membrane." (*Id.* at 619:7-9; JA2977 at 622:2-623:7.)

Shay asked for an affidavit confirming that a PHOSITA would have agreed with their reading of the '382 patent. (JA7639.) Pope submitted a declaration from Gordon Sanghera, then the research director of MediSense. Dr. Sanghera reviewed the literature available in 1983 and opined that a PHOSITA would have regarded a protective membrane as necessary, not merely optional, when measuring in ***whole blood***: a PHOSITA "would not read [the optionally, but preferably language] to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred." (JA2999 at 709:2-13; JA7636-37.) Pope submitted legal remarks along the same lines, explaining that "[t]here is no teaching or suggestion of unprotected active electrodes for use with whole

blood." (JA7643-46.) The '551 patent then issued on October 13, 1998. (Trial Order 7.)

2. The EPO legal briefs

A few years earlier, MediSense's German patent counsel had submitted two legal briefs to the EPO in defense of the EP 0,078,636 ("the '636 patent"), whose specification is largely the same as the '382 patent. (Trial Order 28-29.) That proceeding addressed a prior art reference known as "D1." (JA6832-52.) MediSense's German counsel distinguished the D1 reference because it used the older diffusion-limiting, "semipermeable membranes," whereas the '382/'636 patents use protective membranes *fully permeable* to glucose. (JA6527, JA6532-33, JA6584-86.) The clearest explanation of the type of membrane used in the '382/'636 specification happens to be in the "optionally, but preferably" sentence, which explains that the "protective membrane" is "permeable to water and glucose molecules." It is not thus surprising the sentence was quoted in the EPO briefs.

3. The supposed inconsistency

The district court concluded that Pope had argued to the PTO that the '382 patent *required* a membrane for whole blood, whereas German counsel had argued the opposite to the EPO: "that the 'optionally, but preferably' sentence demonstrated that the '382/'636 invention did *not* need a membrane for measuring

glucose in blood." (Trial Order 26; *see also id.* 26-28.) The district court's reading of the documents is incorrect.

Both the EPO and PTO submissions are consistent with membranes being optional for fluids other than blood, but required for blood. Pope said only that a membrane was required in the '382 patent ***for whole blood.*** (*See, e.g.,* passages quoted in Trial Order 24-25.) Pope never disputed that a membrane was optional for blood plasma, interstitial fluid, and buffer; indeed, he specifically pointed out Example 8's testing of a membraneless sensor in buffer. (Trial Order 25; JA2977 at 623:8-20.)

In the EPO, MediSense never argued that a membrane was optional for ***whole blood.*** Rather, German counsel repeatedly pointed out that "For use on human blood the sensor of Example 7 [Example 8 of the '382] was provided with a protective membrane." (JA6586 ¶ 5; *see also* JA6531.) That directly refutes the idea that MediSense argued a membrane was unnecessary for blood. To the extent German counsel stated that, unlike the glucose-limiting membrane of D1, a membrane was optional, that statement referred to the undisputed fact that a membrane was indeed optional for applications such as interstitial fluid, which was specifically called out in the '636 claims and specification. (JA6540-50.)

4. There was no evidence of bad faith.

Pope testified at length that he did not submit the EPO briefs in the '551 prosecution because he believed they were irrelevant to the issue before the PTO, *i.e.*, whether the '382 specification taught a membrane*less* sensor for *whole blood.*[4] (JA2976-94.) He understood the EPO legal arguments to address an entirely different issue: whether the membrane disclosed in the '382/'636 specification was the same as the semipermeable membrane of the D1 reference. He even consulted on this point with Dr. Sanghera, who had personally participated in the EPO proceedings and was thus very familiar with the arguments to the EPO. (JA3010-11 at 752:24-757:11.) The district court nonetheless concluded that Pope intended to deceive the PTO because Pope "knew or should have known" that the EPO submissions contradicted his statements to the PTO. (Trial Order 33.) But there was no evidence that Pope did not believe his interpretation of the EPO documents, no evidence that he adopted that interpretation in anything other than good faith, and no evidence that he believed his legal remarks to the PTO were false. The district court simply refused to accept that Pope reasonably could have read the EPO legal briefs differently from the court.

[4] At the time, Pope thought "whole blood" and "live blood" were synonymous. (JA2979 at 628:21-629:15.)

As for Dr. Sanghera, he testified that he relied on his counsel Pope to decide whether to submit the EPO legal briefs to the PTO. (Trial Order 36.) The district court nonetheless concluded Dr. Sanghera intentionally committed inequitable conduct merely because he did not discuss those legal briefs in the declaration he provided to the PTO, a declaration that even Defendants' paid witness Dr. Higgins said was "reasonable." (JA3756.)

F. The TheraSense Patents

1. The '164/'225 patents: Smaller sample size

The '164/'225 reference describes a glucose sensor for blood samples smaller than one microliter.[5] (JA8777, Abstract.) Measurement in such a small sample enabled diabetics to measure their glucose less painfully and thus more often. (JA8779:11-23.)

One difficulty with developing measurements for smaller samples was that as the electrodes were brought closer together, the "background signal" increased, degrading accuracy. (JA8787:27-8788:2.) The background signal is the current generated not by glucose reactions but by factors like the "shuttling" of the mediator back and forth through the sample between the electrodes. (*Id.*) The '164/'225 inventors solved this problem by employing either (a) *nonleachable*

[5] The '225 application is the international counterpart of the '164 patent and shares the same written description as the relevant portion of the '164. (JA8777-8859; JA9915-47.)

mediators (*i.e.*, those that do not substantially diffuse into the sample); or (b) *immobilized* mediators (*i.e.*, those that are trapped or bonded to the electrode surface). (JA8786:3-10.) The specification makes abundantly clear that the invention pertains to nonleachable or immobilized mediators. (*See, e.g.*, JA8787:21-8788:2.) The '164/'225 specifications contain no examples with diffusible (or "leachable") mediators, and there is no evidence that the inventors built or tested any such sensor in the research for the '164/'225 specifications. Nor is there evidence that the '164/'225 sensors would have worked using a diffusible mediator without excessive background signal.

2. The '745 patent: Smaller sample size with diffusible mediators

The '745 patent-in-suit describes later research at TheraSense. The '745 inventors developed sensors using ***diffusible*** mediators with acceptable background signals even in a very small sample. (JA8275, Abstract.) The claims of the '745 patent all include a diffusible mediator, along with other elements not disclosed in the '164/'225 reference. (JA8340-42.)

The PTO initially rejected the claims of the parent application of the '745 patent based on the 6,120,676 patent that shares (in relevant part) the specification of '164/'225 references. (JA9772-9774.) TheraSense explained, however, that the '676 specification does not teach diffusible mediators. (*Id.*) The PTO then withdrew the rejection, and the rejection was not repeated during the examination

of the '745 patent itself, despite explicit consideration of the '676, '164 and '225 references. (JA8277-78.) Thus, the PTO rejected the very theory upon which the district based its summary judgment invalidity ruling.

3. The district court's summary judgment order

On summary judgment, the district court held that BD/Nova did not infringe either the '164 or '745 patents because, the court said, the "non-flowing manner" limitation in both patents' claims requires blood to be completely immobilized without even convective flow — even though it is undisputed that all liquids have some amount of convective flow.

The district court also held the '745 anticipated by the '225 on the theory that a sentence in the '164/'225 specification — "Preferably, there is little or no leaching of the redox mediator . . ." — disclosed the use of leachable mediator. Just as with the '382 patent, the district court focused on the word "preferably" in isolation and ignored the context, the specific teachings, and the embodiments of the reference. The district court thought it enough that the "preferably" language "acknowledg[ed] the possibility of using a leaching or diffusing mediator" — despite testimony from Defendants' own expert that the '164 did ***not*** disclose the use of a leachable mediator. (SJ Order 48.)

VI. SUMMARY OF THE ARGUMENT

'551 Obviousness: The district court invalidated claims 1-4 of the '551 patent based on the single phrase "optionally, but preferably" in the '382 specification without regard to the actual technical teachings of the patent, the conventional wisdom at the time, or expert and inventor testimony. That phrase does not teach or enable a PHOSITA to make and use the '551 invention, which constituted an improvement on the '382 invention.

'551 Inequitable Conduct: The district court's fixation on the "optionally, but preferably" sentence carried over to its finding that the '551 patent was unenforceable. This is not a case of withheld prior art, technical data, or test results. Nor is there any separate evidence of an intent to deceive. Abbott's counsel and scientist simply read the EPO briefs differently than the district court. Patents should not be rendered unenforceable, millions of dollars in sanctions should not be awarded, and reputations should not be sullied over good faith disagreements concerning the meaning of lawyer arguments.

'164/'745 Noninfringement: The district court erred in its construction of the "non-flowing manner" limitation by ignoring the prosecution history and construing the term so narrowly as to exclude all possible embodiments.

'745 Anticipation: On *summary judgment*, the district court disregarded the testimony of Defendants' own expert that the '164/'225 specification did not

disclose the '745 invention. That alone created a triable issue of fact. The '225 specification, moreover, disclosed not the '745 technology but the opposite.

VII. ARGUMENT

A. '551 Obviousness

1. Standard of review

Defendants had to prove obviousness by clear and convincing evidence. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984). "On appeal from a bench trial, . . . [t]he ultimate conclusion of whether a claimed invention would have been obvious is a question of law reviewed de novo based on underlying findings of fact reviewed for clear error." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007) (citations omitted).

2. Disclosure: The phrase "optionally but preferably" is not a teaching.

The district court found a major technical advance — a membraneless sensor for whole blood — buried in the phrase "optionally, but preferably" in one sentence in the '382 patent. The district court erred in privileging that phrase over the rest of the specification and all the other evidence. "[A] prior patent must be considered in its entirety, *i.e.*, as a *whole*, including portions that would lead away from the invention in suit." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561,

1568 (Fed. Cir. 1987). A "single line out of" a specification cannot be the focus of the analysis:

> It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to *the full appreciation of what such reference fairly suggests to one skilled in the art.*

Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 448 (Fed. Cir. 1986) (emphasis added).

Read as a whole, the '382 patent has no disclosure of a membraneless sensor for blood. The district court admitted that "the broad teaching" it ascribed to the "optionally, but preferably" phrase "went beyond the specifics of the preferred embodiments." (Trial Order 16.) But "[g]eneral allegations, appearing as a departure from the more specific teachings . . . and devoid of detail" are not teachings. *In re Shuman*, 361 F.2d 1008, 1012 (C.C.P.A. 1966). The district erred in elevating the importance of one sentence, which, under the court's reading, was a "departure" from the specific teachings of the specification, which all ***teach away*** from the '551 invention.

Neither Dr. Turner nor the district court ever explained why a PHOSITA would have focused on a formalistic construction of a single sentence rather than on the technical disclosures of the patent *as a whole*, including Example 8. Dr. Turner himself admitted that words like "preferably" are read by PHOSITAs in the

context of conventional wisdom and the teachings of the entire patent. *Supra* 20-21. The Nankai application also provides objective evidence that the '382 did not teach a membraneless sensor for blood. *Supra* 13-14. That the terms "optional" and "preferable" cannot be taken literally as *technical teachings* is demonstrated by the simple fact that no one has developed a membraneless sensor for live blood in the 20+ years since the '382 patent issued even though a membrane is supposedly just "preferred" for live blood. (Trial Order 18; *see also* JA3750; 3095-96; JA2618 at 333:5-15.)

3. Reasonable Likelihood of Success: There was no proof of an expectation that a membraneless '382 sensor would work in blood.

Even if the '382 patent disclosed the idea of a membraneless sensor for whole blood, the patent did not provide the reasonable expectation of success required for obviousness. Defendants' expert never testified to the issue. The sentence itself is the kind of "general guidance" that is insufficient to create a reasonable expectation on its own. *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). Abbott's expert, Dr. Johnson, provided uncontroverted testimony that a PHOSITA would have in fact expected the '382 sensor not to work in whole blood without a membrane. (JA2736 at 485:18-486:3.) This was the conventional wisdom at the time. Example 8 reinforced that by adding a membrane for whole blood and reporting a 5% oxygen effect for the membraneless

sensor even in buffer. *Supra* 15. This alone should have eliminated any expectation of success.

The district court's insistence that a PHOSITA "would have *known* [] that the electrochemistry would still have worked" for the '382 membraneless sensor in whole blood is flatly inconsistent with the unanimous testimony of the inventors. (Trial Order 17 (emphasis added).) They did not know at the time how to make a membraneless sensor for blood. *Supra* 13. The district court thus concluded that a person of *ordinary* skill would have "known" something based on one sentence in the '382 specification that the inventors — worldwide leaders in the field — did not themselves know.

Moreover, the sensors used in the '551 patent differ from the '382 in many ways other than the mere deletion of the membrane. *Supra* 15-18. There can be no reasonable expectation of success where the '382 patent gives no guidance on how to make sensors that will work in blood without a membrane. *See Medichem*, 437 F.3d at 1165 ("[O]ne must be motivated to do more than merely to 'vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result.'").

4. Enablement: There is no evidence the '382 patent enabled the '551 invention.

The district court ignored a foundational principle in the law of obviousness: it is not enough to merely find a *suggestion* for the invention at issue in the prior art. Rather, "to render a claimed apparatus or method obvious, the prior art must enable one skilled in the art ***to make and use***" the invention.[6] *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (emphasis added). Otherwise, a patent could be invalidated by speculation or casual mention of an idea. Stating that a car "optionally" might be powered by hydrogen fusion would not render obvious a car powered by fusion. Obviousness requires not just that the *idea* for an invention have been obvious, but that it was obvious how to "make and use" the invention. *See Motorola, Inc. v. Interdigital Tech. Corp.*, 121 F.3d 1461, 1471 (Fed. Cir. 1997) ("The district court properly instructed the jury that it must find prior art references enabling."); *In re Kumar*, 418 F.3d 1361, 1369 (Fed. Cir. 2005) ("To render a later invention unpatentable for obviousness, the prior art must enable a person of ordinary skill in the field to

[6] By contrast, it does not matter for purposes of obviousness (as opposed to anticipation) if the prior art reference enables the *prior art* invention itself. *See Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) ("[A] non-enabling reference may qualify as prior art for the purpose of determining obviousness under § 103."). In other words, whether the '382 specification enabled the '382 claims is not the issue (as it would be in an anticipation analysis). The question is whether the '382 patent, combined with the other references, enabled a PHOSITA to make and use the *'551 invention.*

make and use the later invention."); *Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1365 (Fed. Cir. 1998) ("The prior art must be enabling" for obviousness); *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1325 (Fed. Cir. 2005). ("If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to 'inventions' consisting of little more than respectable guesses.")

Defendants offered no evidence (much less clear and convincing evidence) that the sensor of Example 8, or any other '382 embodiment, works without a membrane in whole blood. None of the inventors claim even to have known how to build such a sensor at the time of the '382 specification. *Supra* 13. Indeed, there is no evidence that anyone has ever tried to use any '382 sensor in whole blood without a membrane. There was no basis to presume, as the district court appears to have presumed, that just because the '551 sensors work without a membrane in whole blood, a PHOSITA could rip the membrane off the sensor described in the '382 patent, stick it in whole blood, and have it work. The only evidence is that the sensors described in the '382 would *not* have worked without a membrane in blood. Dr. Sanghera testified that the oxygen sensitivity of the membraneless sensor in Example 8 detected when tested in buffer (with much lower oxygen concentration than blood) would have rendered it ineffective in whole blood. (JA3001 at 717:7-23.) Dr. Hill, one of the '382 inventors, admitted

that "in '82, '83" — a year or more after the application for the '382 — "there were no electrodes that could be introduced into blood without a membrane." (JA3209 at 48:7-10.)

In addressing enablement, the district court opined that "[a]fter the faster chemistry disclosed in the '382 patent, the risk [of fouling] became more theoretical than practical." (Trial Order 17.) No record evidence supported the assertion that the faster '382 chemistry (even if it reduced the *extent* of fouling) eliminated the need for a membrane in whole blood. Indeed, when Defendants' own expert, Dr. Turner, was asked whether "you still have that issue, a concern about fouling" in the '382 patent, he explained that "[f]ouling is still a design feature in these devices because you're still dealing with blood." (JA2531 at 241:12-16.)

The district court further ignored the burden of proof and demanded that Abbott prove precisely how the '551 sensors overcame the fouling problem experienced by the '382 sensors:

> It would be different if the '551 patent disclosed a specific configuration that preserved the membrane's function but without the membrane. Exactly what was disclosed in the '551 patent that compensated for the deletion of the membrane and guarded against fouling? The Court asked this question several times during the bench trial.

(Trial Order 21; 22 n.11.) This was error. Enablement of the '551 was not at issue. And as the patentee, Abbott is not required to know, much less prove, why the '551 invention works. "[I]t is not a requirement of patentability that an inventor correctly set forth, or even know, how or why the invention works." *Newman v. Quigg*, 877 F.2d 1575, 1581 (Fed. Cir. 1989). The issue was whether ***Defendants*** had clear and convincing evidence that the '382 patent taught the '551 invention, including enabling a PHOSITA to build the '551 sensors.

5. Motivation to Combine: There was no reason to combine the prior art references.

The district court erred also in concluding that "[o]ne skilled in the art would . . . have readily thought to combine" various other references with the '382 patent to arrive at the invention of the '551 patent merely because the references were "expressly aimed at the subject matter covered by the '551 patent," i.e., disposable blood glucose test strips. (Trial Order 48-49.) Merely recognizing a problem is not obvious unless there is "a finite number of identified, predictable solutions." *Abbott Labs. v. Sandoz, Inc.*, --- F.3d ---, 2008 WL 4636167, *5, *9-10 (Fed. Cir. 2008). There was no evidence or expert testimony that there were a finite number of solutions to the problem of developing a blood glucose sensor for consumer use, or that the ultimate development of the '551 was inevitable. Moreover, even had there been, there was no explanation given at trial why a PHOSITA would have

combined a sensor that they did not believe would work in whole blood with the other components to produce a "seemingly inoperative" test strip for testing whole blood. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 (Fed. Cir. 2001) ("If references taken in combination would produce a 'seemingly inoperative device,'" the invention is not obvious)).

6. The '551 patent is not just a "deletion of a function."

The district court alternatively held that the '551 patent was obvious because the inventors supposedly did nothing more than remove the membrane from the '382 sensor with a "corresponding deletion of its function," citing to *Richards v. Chase Elevator Co.*, 159 U.S. 477, 486 (1895). (Trial Order 20-22.) The '551 sensors, however, are not just the '382 sensors without a membrane, and one cannot assume that the '382 invention worked just because the '551 did. The '551 sensors are built of different materials, prepared differently, and not intentionally oxidized. *Supra* 15-18.

Moreover, the *Richards* rule applies only where after the omission "the elements retained perform the same function as before." *Richards*, 159 U.S. at 486. *See also Smiths Indus. Med. Sys., Inc. v. Vital Signs, Inc.*, 183 F.3d 1347, 1355 (Fed. Cir. 1999) (reversing obvious finding where remaining elements would not function the same). Here, Defendants offered no evidence that the prior art

sensors could perform the same function without membranes, *i.e.*, measure glucose levels in *whole blood*. *Supra* 15-18.

7. Objective Indicia: The court ignored commercial success.

This court has characterized secondary considerations – including commercial success – as among "the most probative and cogent evidence in the record," observing that "[i]t may often establish that an invention appearing to have been obvious in light of the prior art was not." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988). The district court did not dispute Exactech's commercial success. (Trial Order 50 ("This order assumes all of Abbott's representations regarding the Exactech product were true.").) But the district court, once again, reversed the burden of proof and held that "Abbott ha[d] . . . failed to show the requisite nexus between the claims of the '551 patent and the Exactech product." (*Id.*) But all Abbott had to show was that the Exactech embodied the '551 invention, and that was undisputed. (JA3476:23-3477:5.) *See Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000). Defendants provided no contrary evidence.

B. <u>'551 Inequitable Conduct</u>

As is de rigueur in every patent case, Defendants asserted numerous theories of inequitable conduct against each of the four patents in suit. (JA541-47; JA1414-29.) During the litigation, Defendants abandoned various theories of inequitable

conduct and adopted new ones. Ultimately, the district court accepted one theory: that MediSense's arguments to the EPO in defense of the '636 European patent (counterpart to the '382 patent) were purportedly inconsistent with Pope's argument to the PTO in the '551 prosecution.

1. Legal Standard and Standard of Review

Inequitable conduct requires clear and convincing evidence "that the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) intended to deceive the [PTO]." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). Threshold levels of both materiality and intent to deceive, as well as the underlying facts, must first be proven by clear and convincing evidence. *Id.* The equities must then be balanced to determine whether the conduct was egregious enough to warrant holding the entire patent unenforceable. *See id.*

This Court reviews factual findings on materiality and intent for clear error. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc). An inequitable conduct determination premised upon erroneous findings or a misapplication of law must be reversed. *Id.* at 876-77.

2. Ambiguities and inferences must be taken in Abbott's favor.

As demonstrated below, there was no inconsistency between the EPO and PTO submissions. But to the extent there is any ambiguity in the documents or doubt on this point, ***ambiguity should have been resolved in Abbott's favor.*** It is otherwise improper to draw an inference against the patentee. "Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (emphasis added). An inference must be based on "clear and convincing" evidence, and "must also be the single most reasonable inference able to be drawn from the evidence." *Star*, 537 F.3d at 1366-67.

An entire patent should not be held unenforceable, tens of millions of dollars in sanctions imposed, and the reputation of a patent lawyer destroyed based on, at most, ambiguous characterizations of prior art by a foreign lawyer in an unrelated European patent proceeding.

3. Materiality: MediSense's EPO arguments were not inconsistent with Abbott's PTO statements.

Pope told the PTO that the teaching of the '382 patent as a whole was that a membrane was required when testing ***whole blood*** and that a PHOSITA would have read the "optionally, but preferably" sentence consistent with this teaching.

The district court concluded that two passages from the EPO briefs were inconsistent with Pope's legal remarks to the PTO. (Trial Order 26-29.) But in each passage, MediSense's German counsel argued a completely different point: that any membrane used in the '382/'636 patent was permeable to water and glucose and thus not the diffusion-limiting membrane used in the D1 reference. Nowhere did counsel argue that a membrane was optional for testing ***whole blood.*** The district court's reading of the various briefs consistently ignored the central difference between the two sets of arguments and the distinction between ***blood*** and other fluids such as interstitial fluid, blood plasma, and buffer — all three of which everyone agreed could be tested without a membrane by the '382/'636 sensors.

The two passages are set out in full below. First, from MediSense's January 1994 brief:

> 10. The above object is solved by a glucose sensor as defined in claim 1 of the patent in suit ['636/'382]. Apart from the important feature of utilizing a ferrocene or ferrocene derivative as mediator, another important difference over D1 resides in that the claimed glucose sensor - contrary to that of D1 which requires a membrane - does not have and **must not** have a ***semipermeable membrane*** within the meaning of D1. Contrary to the ***semipermeable membrane*** of D1, the **protective** membrane **optionally** utilized with the glucose sensor of the patent in suit is **not *controlling the permeability*** of the substrate (as set forth above under IV.2), in the membrane of D1 the ***permeability for the***

> ***substrate*** must be kept on a low value to achieve a linear relationship between the measures currency and the substrate concentration in the test solution). Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:
>
> > "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."
>
> See also claim 10 of the patent in suit as granted according to which the sensor electrode has an outermost protective membrane (11) ***permeable to water and glucose molecules***. Finally, ***see Example*** *7* in column 10, lines 19 to 26 reporting that by using such a protective membrane the response time did not increase but from 24 to 60 sec. (without membrane) to 36 - 76 sec. (with membrane). Accordingly, the purpose of the protective membrane of the patent in suit, preferably to be used with in vivo measurements, is a safety measurement to prevent any course particles coming off during use but ***not a permeability control*** for the substrate.

(JA6530-31 (bold in original; bold-italics added).)

As can be seen from the italicized language, the passage is about the difference between the membranes used in D1 (semipermeable) versus those used in the '382/'636 specification (permeable). There are six references to the permeability of the membranes. Nowhere does the passage say that a membrane is not needed for measurement in blood. To the contrary, the passage points the EPO to Example 7 of the '636 specification (Example 8 of the '382 specification), where a membrane was *added* for testing in blood.

The district court focused on the quotation of the "optionally, but preferably" sentence, but German counsel was merely quoting verbatim the clearest disclosure in the '382/'636 specification that the membrane used is, in fact, "permeable to water and glucose." The district court pointed also to the reference to a "protective membrane **optionally** utilized," but that is consistent with the membrane being optional for blood plasma, interstitial fluid, and buffer — examples of which are mentioned in the '382/'636 and were not disputed by Pope before the PTO.

The second passage is similar. Again, MediSense argued the membrane used in the D1 reference was different from the membrane in the '382/'636 specification:

> In the application from which the patent in suit was granted, a membrane never constituted a feature of the independent claim. In fact, a membrane did not appear but in original claim 13 (claim 10 as granted) and is defined as a "***protective membrane permeable to water and glucose molecules***." Column 5, lines 30 to 34 of the patent in suit provides the following information:
>
> > "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules."
>
> It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood ***in order to prevent the***

> ***larger constituents of the blood, in particular erythrocytes from interfering with the electrode sensor.*** Furthermore it is said, that said protective membrane ***should not prevent the glucose molecules from penetration***, the membrane is ***"permeable" to glucose molecules***. This teaches the skilled artisan that, whereas the ***semipermeable membrane of D1*** must be constructed, for example by crosslinking, in such a way that the membrane will in fact ***control the permeability of the glucose*** at the required low value, the purpose of the protective membrane in the patent in suit is **not** to control ***the permeation of the glucose molecules***. For this very reason the sensor electrode as claimed does not have (and must not have) a ***semipermeable membrane*** in the sense of D1. The fact that the same material (cellulose acetate) may be used both for the ***semipermeable membrane*** of D1 and the protective membrane of the patent in suit is not relevant. The decisive feature is the modification (crosslinking) of said material to an extent so as to ***control the permeation of the substrate glucose.***

(JA6585 (italics added).)

As the italicized language shows, this passage also focuses on whether the membrane of the '382/'636 is permeable to glucose. There are at least ten references to the permeability of the membrane. The district court stressed that the passage suggests that the '382 membrane was "optional," but that is consistent with the membrane not being needed for blood plasma, interstitial fluid, or buffer. There is no claim anywhere that a membrane is optional for ***whole blood*** — the only argument that could have been inconsistent with Pope's legal remarks to the PTO or Dr. Sanghera's declaration.

The district court put great emphasis on German counsel's statement that "this disclosure is unequivocally clear." (Trial Order 28-29.) But as Pope explained, that statement is best read as arguing that the "optionally, but preferably" sentence is "unequivocally clear" on the issue before the EPO — that the membrane used is "permeable to water and glucose" — as the sentence immediately following makes readily apparent. (JA2983 at 645:5-25; JA2989-90 at 671:9-673:13.)

Regardless, inequitable conduct should not turn on the interpretation of the phrase "unequivocally clear," or similar subjective phrases. *See, e.g., Scanner Techs.*, 528 F.3d at 1378 (reversing inequitable finding based on disagreement of the term "copious" because it is a "relative determination"). As Judge Easterbrook recognized, basing inequitable conduct on such close interpretation of legal documents is improper because applicants would be forced to guess at their obligations: "Obtaining a patent is not such a game of chance. If it were, the incentive to invent would be seriously eroded." *In re Mahurkar*, 831 F. Supp. 1354, 1381 (N.D. Ill. 1993) (Easterbrook, J., sitting by designation).

The EPO Board itself understood the relevance of the German counsel's submissions to be what type of membrane was used in the specification:

> it is stated that optionally, but preferably when being used on live blood, a protective membrane surrounds the enzyme and the mediator layers, permeable to water and

> glucose molecules. The Board can therefore agree with the Appellant that by a *protective membrane is meant one . . . being substantially freely permeable to glucose and water molecules, and not exercising a diffusion-controlling function as in D1.*

(JA6570-71 (emphasis added).)

It is notable that the only two scientists to testify regarding whether the EPO and PTO briefs were consistent — Gordon Sanghera and Dr. Johnson — both agreed that the submissions were consistent. (JA2744 at 515:20-517:3; JA2745 at 520:16-25; JA3003 at 726:4-726:25.) Defendants' scientific expert Dr. Turner never testified that the briefs were inconsistent.

4. Materiality: Lawyer argument about prior art is not information material to patentability.

The EPO legal briefs did not contain "material information" in the usual sense. Those briefs did not disclose any new prior art, nor any new scientific or technical data relevant to the '551 prosecution. The '382 specification was already well known to the Examiner. The only portion of MediSense's EPO briefs that even arguably could have been relevant to the '551 prosecution was the characterization of the '382/'636 patent and its "optionally, but preferably" language.

Even if there had been some arguable inconsistency between the EPO and PTO submissions, such an inconsistency should not be "material" for inequitable conduct purposes. This Court has previously held that lawyer characterizations

about prior art are *not* material. *See, e.g., Young v. Lumenis, Inc.*, 492 F.3d 1336, 1349 (Fed. Cir. 2007) ("We . . . fail to see how the statements . . .which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact."); *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008) ("Innogenetics' representation of the Cha PCT application amounted to mere attorney argument and our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of prior art.").

The same is true for non-lawyer or inventor argument about the teachings of prior art and the understanding of a PHOSITA. *See Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) ("[T]he inventors merely advocated a particular interpretation of the teachings of the Johnson article and the level of skill in the art, which the Examiner was free to accept or reject."). Even allegedly misleading *affidavits* about the teachings of prior art are not considered material because "[t]he examiner [is] free to reach his own conclusion" about the prior art. *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986).

That reasoning applies equally here: Pope's arguments to the PTO, Sanghera's declaration, and German counsel's arguments to the EPO were all

characterizations of prior art that was already before the examiner. These characterizations were not "material" for inequitable conduct purposes.

Upholding the district court's inequitable conduct finding would greatly expand the burdens on patentees — and the scope of inequitable conduct claims — by requiring disclosure not only of prior art, technical data, factual declarations, and litigation involving the patent at issue, but also any legal brief or correspondence submitted by U.S. or foreign counsel characterizing prior art. Just to take an example, patent counsel who works in a specific technical field would need to comb through all of her submissions every time she filed an application anywhere in the world, for fear that some submission on a prior application could later be characterized as "inconsistent" with her arguments to the PTO.

Moreover, the district court's rationale for requiring disclosure would extend to even submissions by third parties. Any document that a patentee or patent counsel has ever seen that makes an argument arguably inconsistent with a position asserted by the patentee, even a brief submitted by a *third party* in an unrelated foreign patent proceeding or a letter from opposing counsel regarding some prior art could later be deemed "material" to patentability.

Requiring disclosure of every utterance that might be inconsistent with a position the patentee takes before the PTO would constitute a vast and unwarranted

expansion of the law of inequitable conduct. The burdens on patentees, patent counsel — and the patent examiners — would become entirely unmanageable.[7]

5. Intent: Pope's interpretation of the EPO briefs was reasonable and in good faith.

The district court found an intent to deceive on Pope's part because he "knew or should have known" that the EPO submissions were "highly material." (Trial Order 33:24-25.) Not only is there no basis to characterize a few sentences in an EPO legal brief as "highly material," but this is the same gross negligence standard the Court has repeatedly rejected. It is not enough that "a reasonable person in [counsel]'s position should have known of the materiality . . . and disclosed it to the PTO." *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1443 (Fed. Cir. 1991). "Gross negligence is not sufficient. This is a high bar." *Eisai Co. Ltd. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1360 (Fed. Cir. 2008) (internal citation omitted).

Intent simply cannot be inferred from materiality. "[I]ntent to mislead may not be inferred, without more, from the failure to disclose to the patent examiner known, highly material information." *Judkins v. HT Window Fashion Corp.*, 529 F.3d 1334, 1343 (Fed. Cir. 2008). The information here — characterizations of the

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[7] Even if this court were to adopt the district court's sweeping expansion of the duty of disclosure, neither Pope nor Dr. Sanghera could have foreseen this expansion of the law back in 1997, and therefore cannot be deemed to have acted with the deceptive intent necessary to establish inequitable conduct.

'382 patent to the EPO — had at most a very limited materiality, providing even less basis for inferring intent. *See, e.g., Purdue Pharma L.P. v. Endo Pharms. Inc.*, 438 F.3d 1123, 1134-35 (Fed. Cir. 2006) ("[W]hen the materiality of the undisclosed information is relatively low, there is less basis for inferring intent.").

Put another way, even if it disagreed with his reasoning, the district court should have given Abbott's prosecuting attorney the benefit of the doubt in determining whether to submit a reference. *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1585 (Fed. Cir. 1996) (giving patentee benefit of the doubt for concluding reference was immaterial even though "[p]rudence would have dictated otherwise"). Rather than do that, the district court found inequitable conduct based on its view that in ambiguous circumstances patent counsel "should err on the side of disclosure, not nondisclosure." (Trial Order 34.) That was error. Inequitable conduct "should be determined in light of the realities of patent practice, and not as a matter of strict liability whatever the nature of the action before the PTO." *N. Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990). Inequitable conduct relates not to minor errors or misunderstandings, but only to egregious and *intentional* misconduct. "[I]t is also inequitable to strike down an entire patent where the patentee only committed minor missteps or acted with minimal culpability or in good faith." *Star*, 537 F.3d at 1366.

Pope had a very good explanation for his conduct. Pope testified that he understood MediSense to have argued to the EPO that the D1 reference required a semipermeable membrane while the '636/'382 patents used a permeable, protective membrane — an issue entirely irrelevant to the '551 proceedings. Pope did not read the EPO briefs as addressing whether the '636/'382 patent taught a membraneless sensor for ***blood***. Throughout his testimony and cross-examination, Pope's explanation was never impeached: in his mind, "what was at issue in the EPO and was addressed by this document was the question of whether or not . . . the protective membrane, required by the '636 patent in some instance is [sic] was distinguishable from the semipermeable membrane taught by reference D1 to be a diffusion-limiting membrane." (JA2982 at 643:19-25.)

The district court dismissed Pope's explanation because it was inconsistent with how the district court read the EPO documents. But the issue was not whether the district court agreed with Pope's reading of the EPO legal briefs. The only question was whether Pope's explanation of his reading of the EPO briefs was "plausible" — whether the EPO briefs are subject to his reading, regardless of whether that is the reading the district court preferred. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1382 (Fed. Cir. 2006) ("Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible."). There is no evidence in the

record suggesting that Pope's reading of the documents was so improbable as to render his explanation implausible.

Even if Pope did not provide a credible explanation for his conduct - which he did - that still would not be enough to infer intent. A "failure to disclose a prior art device to the PTO, where the only evidence of intent is a lack of a good faith explanation for the nondisclosure, cannot constitute clear and convincing evidence sufficient to support a determination of culpable intent." *M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co.*, 439 F.3d 1335, 1341 (Fed. Cir. 2006); *see also Star Scientific,* 537 F.3d at 1368 ("The patentee need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence."). Here, where Pope gave a fully plausible explanation for his non-disclosure decision that was never impeached at trial, there simply was no tenable basis for the Court's finding of culpable intent.

6. Intent: Dr. Sanghera was entitled to rely on Section 1.56.

Dr. Sanghera fully discharged his obligations under Section 1.56 to the letter. Under 37 C.F.R. Section 1.56(d), "[i]ndividuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor." Dr. Sanghera did exactly that. (JA3011 at 757:9-11.)

He left it up to patent counsel to make the "key decisions on the legal side of things." (JA3015 at 774:14-18.)

The district court, however, decided that Dr. Sanghera could not rely on 1.56, supposedly because a scientist who submits a declaration to the PTO is not entitled to rely on his or her lawyer to decide what should be disclosed to the PTO and, in this case, interpret the EPO submissions. (Trial Order 36-37.) Rather, the district court insisted that Dr. Sanghera had an obligation to substitute his own supposed reading of the EPO legal briefs for his lawyer's reading of them. This approach has no basis either in 1.56 or anywhere else in the law and would undermine the advisory role of counsel.

The district court's conclusion that Dr. Sanghera's declaration was "false and misleading" (*id.*) also finds no support in the record. As discussed above, there is no evidence (other than the district court's own "reading" of the patent) that a PHOSITA would have read the "optionally but preferably" sentence to disclose membraneless sensors for blood, much less clear and convincing evidence that the declaration was ***knowingly*** false. *Supra* 30-37. To the contrary, Defendants' own witness testified that Dr. Sanghera's statements were "reasonable." (JA3756.) As discussed above, Dr. Sanghera's representation that a PHOSITA would not have read the "optionally, but preferably" sentence in the '382 patent to disclose a membraneless sensor for blood is amply supported by the

'382 specification, the testimony of the inventors themselves, and the Nankai patent.

C. The "Non-Flowing Manner" Limitation of the '164 and '745 Patents

The district court held that BD/Nova's test strips do not infringe the '164 or '745 because they do not satisfy the court's construction of a claim limitation common to both patents: "holding the sample in a non-flowing manner within the sample chamber of the analyze sensor." (SJ Order 21-22.) The district court initially construed "non-flowing" to mean "the sample is not moving in the sample chamber during the measurement." (JA13833-34.) At summary judgment, the district court elaborated and held that the limitation is not satisfied if there is *any* movement within the sample during measurement — even the convective motion present in all liquids. (SJ Order 21-24.)

Not surprisingly, the district court's construction finds no support in the prosecution history, the specification, or common sense.

1. The district court ignored the prosecution history.

The "non-flowing manner" limitation was added to the '164 patent (and its parent application) to distinguish the Niwa reference. (JA13747-48; JA13753-54; JA13777-78; JA13781; JA13791; JA13793-98; JA13800-02.) Niwa discloses a "flow cell" where the sample continuously flows through the sensor during measurement. (JA13748.) The '164 invention, by contrast, holds the sample in a

chamber, preventing it from flowing out until after the measurement. To capture that distinction, the inventors added the "non-flowing manner" limitation to the '164 claims. That was sufficient to traverse a rejection over Niwa. (JA13810.) As the Examiner noted in the Notice of Allowability for the parent application: "This prior art is distinguished from applicant's instant invention by disclosing only flow-through embodiments." (JA13805-06.) Nothing in the prosecution history (or the patent) suggests the limitation was added to require the sample to be otherwise "immobilized" in the chamber. The point was to indicate that the sample does not continuously flow through during measurement; that was all.

The district court should have deferred to that prosecution history: "the prosecution history may be given substantial weight in construing a term where that term was added by amendment." *Board of Regents v. BENQ America Corp.*, 533 F.3d 1362, 1369 (Fed. Cir. 2008); *see also Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) ("[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention.").

2. The district court's construction violates the laws of physics.

The district court's construction violates the laws of physics. The uncontroverted evidence is that "[t]here is always diffusion and at least a minor amount of convection occurring within any fluid. If the non-flowing manner

limitation of the '164 and '745 Patents were to exclude all of these types of motion, then no fluid could ever meet that claim limitation." (JA10553 ¶ 60.) Patents should not be construed to be physically impossible if a workable construction is at least equally plausible. *Cf. Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1372 (Fed. Cir. 2002) (noting that, where it is possible to do so, claims should be read to preserve their validity).

3. The district court misread the specification.

The plain meaning of the term "flow" is "to issue or move in a stream." Merriam-Webster's Collegiate Dictionary (10th ed. 1999). "Non-flowing" thus means not "moving in a stream." It does not mean absolutely immobile. Damming a stream stops it from "flowing," but does not immobilize the water, which continues to have internal motion — like all liquids.

The '164 specification itself repeatedly analogizes the sample to a stream. For example, in discussing one embodiment: "As the fluid stream flowed through the sensor, a steady-state current proportional to the lactate concentration was measured. At periodic intervals the fluid flow was stopped and current was allowed to flow between the electrodes" (JA197.30 23:7-13). The district court misread the word "stopped" to mean the sample could not have any movement of any kind. But as with a dam on a stream, "stopping" the "flow" means simply preventing the sample from continuing to flow out of the chamber. The accuracy

of the measurement does not depend on whether the sample continues to have internal motion. Put another way, the court's construction could be corrected by changing a single word: rather than "not moving ***in*** the sample chamber," the patentee used non-flowing to mean "not moving ***through*** the sample chamber."

D. Anticipation of the '745 Patent

1. The '225 reference did not disclose using diffusible mediators.

The district court similarly focused on isolated words, out of context, in the '164/'225 specification to find the '745 patent anticipated. The district court misread the '225 reference as "clearly disclos[ing] the use of a diffusible redox mediator as a *means of practicing the disclosed invention.*" (SJ Order 48 (emphasis added).) In fact, the evidence and expert testimony demonstrated that the diffusible mediators are not an aspect of the '225 invention.

First, the abstract and summary of the invention, both of which the district court ignored, make clear that the '225 invention does not encompass leachable or diffusible mediators. The abstract describes a sensor having "a working electrode coated with a *non-leachable* redox mediator." (JA8777 (emphasis added).) The summary of the invention similarly explains that "the invention utilizes a *non-leachable* redox mediator, preferably an air-oxidizable mediator, and preferably immobilized on a working electrode." (JA8779:29-8780:1 (emphasis added).) As this Court has often noted, the abstract and summary of the invention typically

describe the invention most ***broadly***. *See C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 864 (Fed. Cir. 2004) ("Statements that describe the invention as a whole are more likely to be found in . . . the Summary of the Invention.").

Second, the very passage the district court relied upon clearly teaches only non-leachable mediators:

> A sensing layer 32 containing *a non-leachable (i.e., non-releasable) redox mediator* is disposed on a portion of the working electrode 22. *Preferably, there is little or no leaching of the redox mediator* away from the working electrode 22 into the sample during the measurement period, which is typically less than about 5 minutes. *More preferably, the redox mediators of the present invention are bound or otherwise immobilized* on the working electrode 22 to prevent undesirable leaching of the mediator into the sample.

(JA8787:21-27 (emphasis added).) The district court focused solely on the word "preferred" in the second and third sentences and concluded (as with the '382) that the patent was implicitly teaching the opposite of what is discussed. (SJ Order 48.) The district court ignored, however, the language of the ***first*** sentence of the paragraph, which does not contain the word "preferably." That sentence is the *broadest* description of the mediator being taught, with the two following sentences progressively *narrowing* the mediator to preferably have very minimal leaching or better yet being immobilized.

The *entire* passage thus has the following meaning. The first sentence describes the mediator of the invention as non-leaching. The second sentence indicates that, preferably, an optimal non-leaching mediator is used, *i.e.*, one with "little or no" leaching. The third sentence suggests that, most preferably, the mediator is not only of the optimal non-leaching variety, but also that leaching is further prevented by immobilizing the mediator on the electrode. None of this describes the use of a *leaching* mediator.

To the contrary, the specification (in a portion disregarded by the district court) proceeds to explain that "a diffusing or leachable (*i.e.*, releasable) redox mediator is not desirable" in the sensors with a small sample size "because a large background signal is typically produced." (JA8787:27-32.) This made clear that a diffusible or leachable mediator is not taught for use *in the invention.*

2. The testimony of *Defendant's* expert created a triable issue of fact.

In addition to being unsupported by the intrinsic evidence, summary judgment was further improper for the simple reason that Bayer's own expert, Dr. Turner, testified that the '164 (which, as noted, shares in relevant part '225 specification) "tells you specifically not to use diffusible mediators." (JA9736:8-16.) When asked if there is "sufficient information in the patent for one of ordinary skill in the art to make" a sensor with a diffusible mediator, he opined, "[n]ot the teachings of the '164 patent, no." (JA9737:10-16.) "This clearly tells

me don't use a diffusible mediator and that's really an end to it." (JA9739:14-16.) According to Dr. Turner's expert report, "the '164 patent specifically teaches against the use of diffusible mediators in electrochemical sensors" where the electrodes are closely spaced, because "a large background is typically produced." (JA11315.) As characterized by Dr. Turner: "The problem of background signal created by shuttling of the diffusible mediator is the very problem the '164 Patent purports to solve." (*Id.*)

The district court discounted Dr. Turner's testimony as merely saying that the '225 reference "taught away" from diffusible mediators, citing *Upsher-Smith Laboratories, Inc. v. Pamlab, L.L.C.*, 412 F.3d 1319, 1323 (Fed. Cir. 2005), for the principle that "the question whether a reference 'teaches away' from the invention is inapplicable to an anticipation analysis." But, Dr. Turner testified not just to teaching way but rather that the '225 reference did not disclose the use of diffusible mediators with the invention and had *no teachings* for making the invention work with diffusible mediators: "[W]hen you read this section of the patent in context, it's clearly telling me that *the inventors want to talk and are talking about immobilized mediators and not diffusible mediators*." (JA9741:20-24; (**EMPHASIS ADDED**); *see also* JA9736:17-20; JA9738-41.)

The facts of *Celeritas Technologies, Ltd. v. Rockwell International Corp.*, 150 F.3d 1354 (Fed. Cir. 1998), also cited by the court below, illustrate this critical

difference. In that case, this Court found that, although a prior art article disparaged the data transmission method of the patent in suit, the article clearly disclosed the use of such a method and *indicated that the author had performed it.* Those are not our facts.

3. The '225 patent did not disclose or enable the "background signal" limitation of the '745 patent.

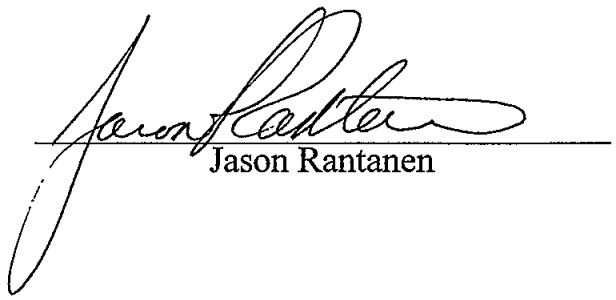
Moreover, there is no evidence the '225 reference disclosed or enabled the limitation in the '745, not present in the claims of the '225 reference, that the "background signal that is generated by the redox mediator [be] no more than five times a signal generated by oxidation or reduction of" a specified amount of glucose. (JA8340 at 61:57-61; JA8341 at 64:63-67.) Defendants provided no evidence that the '225 reference disclosed or enabled sensors *using diffusible mediators* that met this background signal limitation. Thus, the '225 reference cannot anticipate the '745.

VIII. CONCLUSION

For each of the foregoing reasons, Abbott respectfully requests reversal of the judgments invalidating the '745 and '551 patents and finding the '551 patent unenforceable and that judgments in Abbott's favor on those issues be mandated. Abbott also respectfully requests reversal of the judgment of non-infringement of the '164 and '745 patents.

DATED: November 4, 2008

Respectfully submitted,



Jason Rantanen

ADDENDUM INDEX